Chapter 9 Quality System

9-1. Scope

This chapter defines procedures and responsibilities for the ISM Quality System (QS), Warranty Program (WP) and Report of Discrepancy (ROD).

9-2. Applicability

These procedures are applicable to all activities and organizations participating in an ISM repair program.

9-3. Quality System bidding eligibility requirements

Maintenance Activities (MA) must have an ISO 9002 quality system manual completed and approved by the NSMM in order to bid on National and Regional COE Repair Programs. MA will not be eligible to compete for Regional COE or National work if they fail to meet the Quality System audit requirements. Quality System requirements for new sites will be evaluated on a case by case basis by the NSMM.

9-4. Quality System Background and Concept

a. The International Organization for Standardization (ISO), headquartered in Switzerland develops and promotes worldwide quality compliance programs. These programs, including ISO 9002, employ planning, process control, and continuous improvement measures to assure customer satisfaction with products produced and/or services provided. ISO 9002, adapted by the U.S. Army Commands, is a proactive quality system that uses process information to prevent occurrence of nonconforming products/services. Better quality is possible at lower cost, since there will be fewer nonconforming products/services and less rework. The ISO objective is customer satisfaction, which means meeting customer quality requirements at the lowest possible cost. This objective is accomplished through a quality system that addresses all activities necessary to assure confidence in the process used to produce a product. "Product" includes both goods (e.g., hardware, software, processed materials, etc.) and services (Reference enclosure 9-1).

b. In accordance with ISO 9002, a Quality System consists of a Quality Manual defined as a Level A document, implementing procedures defined as Level B documents, and supporting documents defined as Level C documents, such as Quality Plans, job descriptions, specific work procedures, checklists, charts, graphs, records and reports. The entire set of documentation (levels A, B, and C) comprise the quality system (QS). Once documented, the QS must be implemented and maintained. The key ingredient for effective QS is pro-active management support and upper management commitment. QS effectiveness is measured by internal/external audits and customer satisfaction.

c. ISO defines a Quality Plan as a document that sets out specific quality practices, resources, and sequences of activities relevant to a particular product, project, or contract. Quality plans provide a mechanism by which to connect existing generic quality system procedures to specific requirement of the product, project, or contract. Plans may dictate the development of a comprehensive set of procedures or instructions over and above those that already exists; additional procedures or work instructions may be required. Ranging from simple (e.g., for an simple piece-part) to lengthy and detailed (e.g., for a complex product), quality plans in either case must follow the requirements of your own quality system and reference applicable procedures. Areas that should be considered for inclusion in a quality plan includes: purpose/scope; definition/references; document control; schedule of equipment, including quality activities; flowcharts; descriptions of inspection and testing, including methods and equipment; customer acceptance criteria; safety/reliability factors; and packaging and storage information.

9-5. QS/WP approach

a. ISM national repair programs - National repair programs are funded by the AMC MSCs. As a result, MSCs have a recognized responsibility to monitor all aspects of ISM national repair programs, including QA/WP issues. The MSCs may, in coordination with the NSMM, and RSMM/TSMM/LSMM, perform quality system visits at ISM maintenance activities that conduct repair programs for their respective equipment. Other activities include, but are not limited to, resolving problems or complaints, developing/refining quality system plans and strategies and initiating/continuing working relationships with repair activity personnel. Depending on circumstances, the NSMM may accompany visiting teams. The RSMM/TSMM have the option of accompanying or participating in the team visits. Upon

completion of the visit, the MSCs will provide findings/recommendations to the NSMM. NSMM will forward the report through the ISM management structure to the maintenance activity. Specific ISM National Repair Program QA/WP procedures are discussed in paragraph 9-6.

b. ISM regional repair/COE programs - The primary advocates for QA/WP efforts during ISM regional repair/COE programs are the MA/LSMM/AMM. The LSMM/AMM must ensure that all ISM maintenance activities comply with the prescribed ISO 9002 standards. The MA has the overall responsibility to develop, execute, and manage the quality system. The RSMM/TSMM and NSMM may periodically audit quality programs to track compliance and resolve any noted issues. RSMM/TSMM and LSMM/AMMs may monitor all maintenance activities' Levels A, B and C documentation for compliance with ISO 9002 requirements and execution of annual internal audits (Reference paragraph 9-11). Specific regional COE QA/WP procedures are discussed in paragraph 9-9.

9-6. Quality system management responsibilities

a. ISM Corporate Board

(1) Resolves Quality Assurance (QA) and Warranty Program (WP) issues elevated from the NSMM.

(2) Approves/disapproves revisions to the ISM QA/WP procedures presented by the NSMM.

(3) Authorizes the NSMM to approve/disapprove minor QA/WP procedural changes.

b. NSMM

(1) Serves as Program Manager for ISM QA/WP programs. The NSMM is charged with managing the ISM QA/WP program. The NSMM coordinates with AMC MSCs, RSMM/TSMM and/or other sources for expertise to carry out this mission.

(2) Reviews, makes recommendations and gives final approval to all maintenance activities Level A Quality Manuals (QM).

(3) After initial quality manual approval, the NSMM may conduct a desk side audit of Level B implementing instructions and selected Level C supporting documentation and provide an assessment of the documented quality system to the RSMM/TSMM.

(4) Conducts external quality system audits.

(5) Resolves QA/WP issues elevated from the RSMM/TSMM and MSC.

(6) Assists the Corporate Board in resolving issues raised from the RSMM/LSMM level.

(7) Serves as the proponent for the ISM quality system Audit and Assistance Program (external audit) to ensure ISO 9002 compliance.

(8) Coordinates through RSMM/TSMM for external audit reviews.

(9) Monitors internal audits and follow up corrective actions.

(10) Establishes and maintains National Product Quality Deficiency Report (PQDR) database and monitors regional/theater PQDR databases.

(11) Maintains quality system historical files for 3 years, including Level A documentation, quality system training and results of external audits. Maintains copies of all approved quality manuals and internal audit corrective action reports. Establishes and maintains an internal audit database.

(12) Approves/disapproves all minor QA/WP program system changes.

(13) Forwards copies of all completed National PQDRs to the appropriate AMC MSC quarterly.

(14) Provides ISO 9002 quality system training commensurate with funding availability.

(15) Compares Quality Plans for basic consistency for product lines that appear in two or more regions/theaters.

c. AMC MSC

(1) Coordinate with the NSMM on ISM QA/WP policy.

(2) Fund MSC costs associated with performance of on-site Audit and Assistance Program reviews.

(3) Provides subject matter expert (SME) team members who are familiar with the ISO 9002 procedures and checklists to the NSMM for assistance in the conduct of external audits.

(4) Coordinates all unresolved QA/WP issues with the NSMM.

(5) Monitors national PQDRs in accordance with standard practices as a program assessment tool.

(6) Informs the NSMM office of all proposed MSC visits to ISM repair activities.

d. RSMM/TSMM

(1) Coordinates with LSMM/AMM for NSMM external audit visits.

(2) Participates in assistance visits as required.

(3) Monitors regional/theater QA/WP programs.

(4) Elevates all unresolved QA/WP issues to the NSMM.

(5) Provides access to all PQDRs ISM automation tables/databases to the NSMM.

(6) Forwards all draft Level A Quality Manuals from maintenance activities to the NSMM for review and approval.

(7) Accomplishes QA actions for national ISM repair programs as outlined in paragraphs 9-6 and 9-7 and regional/theater programs as outlined in paragraphs 9-8 and 9-9.

(8) Forwards maintenance activity formal internal audit results to the NSMM.

(9) Forwards the NSMM assessment of the maintenance activities documented quality systems to the LSMM/AMM.

(10) Reviews quality plans for consistency with paragraph 9-3.c.

e. LSMM/AMM

(1) Monitors and assesses all ISM QA/WP program(s) in their area of responsibility.

(2) Coordinate with maintenance activities for all Quality Manuals and forward copies of the manuals through the RSMM/TSMM to the NSMM.

(3) Coordinates through RSMM/TSMM for NSMM external audit visits.

(4) Notifies the RSMM/TSMM of any PQDRs, RODs and loss of capability, which result in a line stoppage lasting longer than 24 hours.

(5) Provides completed PQDRs to the RSMM/TSMM in accordance with paragraphs 9-6 (national) and paragraph 9-8 (regional).

(6) Coordinates with the MA and provides the RSMM/TSMM with a schedule when the Quality Plans will be submitted.

(8) Assures that maintenance activities conduct annual formal internal audits.

(9) Furnishes maintenance activities' formal Internal Audit results to RSMM/TSMM and forwards results of all internal audits and actions taken to the RSMM/TSMM.

(10) Coordinates with maintenance activities in responses to External Audits and provides responses to RSMM/TSMM.

(11) Forwards the NSMM assessment of the maintenance activities' documented quality system received through the RSMM/TSMM/LSMM/AMM to the appropriate maintenance activity.

(12) Maintain QA/WP historical files for 3 years, including results of internal and external audits, regional and national PQDRs, maintenance activity quality manuals, and documentation pertaining to problems impacting quality.

f. Maintenance Activities

(1) Establishes and manages a quality system in compliance with ISO 9002.

(2) Conducts an annual internal audit of all maintenance related quality system functions.

(3) Forwards findings of the internal audits and actions taken to the LSMM/AMM.

(4) Ensures historical files are kept IAW prescribed Regulations/ Local SOP.

9-7. National quality assurance procedures

a. PQDRs on national warranty work will be used to identify and correct quality deficiencies and trends within the repairing activity. PQDRs are prepared by the owning unit and submitted through the LSMM/RSMM/TSMM to the NSMM. Repairing MA will notify the NSMM, through the LSMM/RSMM/TSMM, if there is a loss of capability to meet QA/WP compliance for National Repair Programs. Any repairing MA receiving a PQDR for national warranty work will notify the NSMM through the AMM/LSMM/RSMM/TSMM and provide them with a copy of the PQDR. The investigation of PQDRs with the corrective and preventive actions taken will be in accordance with the repairing activity's Quality Manual (ISO 9002). Upon completion of the quality review process, a copy of the findings and actions taken for each PQDR will be forwarded by the repairing MA through the AMM/LSMM/RSMM/TSMM to the NSMM. The NSMM will establish and maintain a PQDR database. NSMM will forward all findings to the appropriate AMC MSC.

b. PQDRs must meet the following criteria to be considered valid: (PQDRs not meeting the criteria may not be valid and will be returned without action.)

(1) The component failed within the warranty period specified in the repair program SOW (Reference enclosure 9-3).

(2) Prior to removal of the component from the end item, an LAR/MA QC inspector performed an on-site inspection of the item. When this is not feasible (for example, the unit is involved in a field training exercise, LAR/MA QC inspector is not available, or otherwise deployed from home station), the unit should segregate the item and initiate a warranty claim at the earliest opportunity.

(3) The item was returned to the repairing activity for warranty repair unless an agreement was reached between the owning activity and the repairing activity on where the repair should be accomplished.

c. The following documents will be shipped with each repaired item:

(1) National Warranty Information Fact Sheet. (Reference enclosure 9-3)

(2) Final Inspection Test Results appropriate to the item (i.e., Dynamometer, EQUATE) signed of by the operator/QC.

(3) Serviceable Tag, DA Form 1574, attached to the component.

(4) Oil Analysis Request Form, DA From 2026, with results annotated. (If applicable)

(5) Maintenance Request Form, DA Form 2407 or STAMIS generated form used in lieu of.

(6) Component Removal and Repair/Overhaul Record, DA From 2410 (Selected Aviation Items Only)

9-8. National warranty procedures

a. Typically, warranties commence when the organizational maintenance activity/DSU first places the item in service. Failures caused by misuse, mishandling, improper installation, improper operation, unauthorized repairs or unauthorized alterations are not covered by the warranty. The terms and conditions of a warranty for a National Repair Program will be specified in the SOW. Under the SOW, the ISM COE will complete applicable portions of a National Warranty Information Fact Sheet (Reference enclosure 9-3). If the warranty is not specified in the SOW, there is no warranty requirement.

b. The organizational maintenance shop, direct support unit (DSU), or other MA tasked to install the item will activate the warranty. If the item fails under warranty the maintenance shop personnel will use the information provided in the National Warranty Information Fact Sheet and initiate a PQDR in accordance with DA PAM 738-750 or DA PAM 738-751 (Aviation). Information contained in the ISM warranty information fact sheet (Reference enclosure 9-3) packing envelope will guide the process.

(1) The LAR or MA QA/QC will verify applicability of the ISM warranty, assist the unit in preparing the PQDR and help arrange for inspection of the failed item. Multiple types of inspectors depending on the situation (i.e., supporting installation LAR or quality control inspector) may do the inspection. The PQDR will be presented to the inspector upon arrival for the on-site inspection. The LAR or MA QA/QC inspector will inspect the item while it is still installed on the component/end item. If the QC inspector validates initial failure, he or she must complete block 22 of the SF 368 by writing the words "INITIAL FAILURE-YES", sign and enter the inspection date. The QC inspector will provide five (5) copies of the PQDR to the unit and send one (1) copy to the supporting LSMM.

(2) The warranty proprietor (original repairing MA/AMM/LSMM/Depot identified in the warranty fact sheet) may make the decision to fund and have the item repaired locally for minor repairs or have the failed item shipped back to the repairing MA/AMM/LSMM/Depot for repair. If the repairs are not minor in nature or if the issue of warranty applicability is unclear, the item must be returned to the ISM repairing activity (LSMM/AMM/Depot).

(a) The MA will coordinate with their supporting AMM/LSMM and supply activity to deliver the item, along with DD Form 1348-1, a DA Form 2407/5504 and two (2) copies of the PQDR, to ship to the repairing LSMM/AMM/Depot. The supporting AMM/LSMM will also notify the repairing LSMM/AMM/Depot and RSMM/TSMM of the warranty failure and furnish them with a copy of the PQDR. The RSMM/TSMM will inform the NSMM.

(b) The repairing AMM/LSMM/Depot will review the PQDR, inspect the item to determine if the repairs are covered by the warranty, and initiate repair. If the item failed due to poor workmanship or a mechanical defect and the ISM warranty covers the failure, the applicable COE will be responsible for paying all costs associated with the repair. If the item failed due to misuse, mishandling, improper installation, improper operation, unauthorized repairs or unauthorized alterations, the warranty coverage will be nullified. In those instances, the owning installation will be charged for repairs.

(3) The repairing MA/AMM/LSMM will review the PQDR and provide a copy with actual findings to the owning activity and the RSMM/TSMM. The RSMM/TSMM will forward a copy of the completed PQDR to the NSMM. The NSMM will maintain a PQDR database and coordinate with the appropriate MSC Integrated Material Management Center.

(4) If the owning organization takes exception to final disposition of the PQDR, the matter will be elevated to the RSMM/TSMM for resolution. In the event the RSMM/TSMM cannot resolve the issue, the matter will be referred to the NSMM. The decision by the NSMM is final. The issue should be resolved within 45 days from the date the repairing maintenance activity receives the PQDR.

c. Validated PQDRs received on National Program work will activate a review of work procedures used even if the program is completed. A copy of findings and recommendations will be forwarded by the repairing maintenance activity through the LSMM/AMM/Depots to the RSMM/TSMM. The RSMM/TSMM will forward a copy to the NSMM. An external investigation by the RSMM/TSMM will be initiated when three (3) or more MA faults are received in a 6-month period on the same NSN. A copy of the findings and recommendations will be forwarded to the NSMM. Six (6) or more valid PQDRs resulting from workmanship, within a year period starting with the date of the first PQDR, will initiate an external investigation by the NSMM. Reoccurring PQDRs resulting from workmanship could result in the loss of future National Program work.

9-9. Regional/COE warranty procedures and responsibilities

a. ISM COEs warrant regional repair program items will be free from workmanship and mechanical defects at the time the items are first installed/put in service and for thirty (30) days after installation. As a sign of this commitment to quality work, the warranty covers the costs to ship failed items to the repairing ISM MA, repair them to serviceable condition and then return them to the owning GS/RX account or originating activity. Failures caused by misuse, mishandling, improper installation, improper operation, unauthorized repairs or unauthorized alterations are not covered.

b. The ISM COE will register the warranty when the repair job order is completed (DTE-CMPL) by completing applicable portions of a Regional Warranty Information Fact Sheet (Reference enclosure 9-4). The COE will over-pack the Warranty Information Fact Sheet in a fluorescent orange packing envelope and attach it to the item along with shipping documents and all test results signed off by a QA/WP representative. The outside will be marked in accordance with paragraph 9-12. If a failure occurs, the installing unit/activity will use the Regional Warranty Information Fact Sheet to activate the warranty and subsequently report a warranty claim.

c. The organizational maintenance shop, direct support unit (DSU) or other MA tasked to install the item will activate the warranty if the item fails on installation or within thirty (30) days after installation. Maintenance shop personnel will use the accompanying documentation information (Reference 9-13) in accordance with DA PAM 738-750 or DA PAM 738-751 (aviation) for this purpose. The process will be guided by the information contained in the Regional Warranty Information Fact Sheet inside the packing envelope. The following information addresses specific responsibilities for managing the ISM COE/Regional warranty process.

d. Responsibility of the Owning LSMM/AMM

(1) Establish local procedures for the customer to contact a quality assistance representative when a suspected QDR failure occurs. (The process will be documented in their quality system level C procedure.)

(2) Establish local procedures for notification of and coordination with the supporting LAR when a suspected failure occurs. (The process will be documented in their quality system level C procedure.)

(3) Make an initial assessment on receipt of the PQDR to determine if the item should be returned to the COE LSMM/AMM. This decision will normally be made if repairs can be accomplished quickly and inexpensively. Disagreements will be arbitrated by the RSMM/TSMM. If the decision is that the item will be repaired by the owning LSMM/AMM, the COE LSMM will report the agreement via e-mail to the RSMM/TSMM and owning LSMM/AMM. The owning LSMM/AMM will charge the cost to repair to the repairing COE LSMM/AMM MIPR and provide all documentation of the quality investigation and findings to the COE LSMM/AMM and RSMM/TSMM (Reference enclosure 9-5). If the decision is to return the item to the repairing activity, the owning LSMM/AMM will direct the GS RX or supply activity to deliver the item, along with the DD Form 1348-1, DA Form 2704/5504 and two copies of the PQDR, to the local shipping facility for shipment to the repairing LSMM/AMM/Depot.

(4) Intensively monitor all PQDRs received to determine if the item is going to be returned to the repairing maintenance activity IAW the regional PQDR timeline (Reference enclosure 9-6). Notify the COE LSMM/AMM and RSMM/TSMM via E-mail when an item will not be returned.

(5) Coordinate with the installation reparable item exchange supporting SARSS-O account manager to ensure that items identified as PQDRs are not turned in as excess.

(6) Coordinate with the installation reparable exchange account managers to ensure the LSMM/AMM is notified when a PQDR unserviceable item return is processed.

(7) Coordinate the roles of the Maintenance Activity QA/QC representative and supporting LAR, who are critical to the success of the PQDR process. They will examine the failed item to determine the type of failure. They may be the last maintenance personnel to examine the item. They should identify the source of repair of the item and indicate how that the SOR determination was made (i.e., label on the component or Regional Warranty Information Fact Sheet in the container). The procedure of identification should be annotated on the SF 368 and, if possible, all identifying documentation should be attached to the SF 368 copy and returned to the owning LSMM/AMM.

(8) The supporting LSMM will coordinate with the supply support activity to deliver the item with supporting documentation.

(9) Provide the results of the PQDR investigation to the initiating unit Battalion/05 Level Commander or State Maintenance Officer and supporting LAR (Reference enclosure 9-5).

(10) Elevate any concerns or disagreement on PQDR results to the RSMM/TSMM for further review and resolution.

(11) Designate a point of contact (POC) within the LSMM/AMM office to serve as the interface with the RSMM/TSMM and other LSMM/AMMs regarding PQDRs. This POC is responsible to ensure PQDRs received by the LSMM/AMM are responded to IAW the Maintenance Activities Quality System and BPM. Notify the RSMM of the POC name and phone number of the designated POC to perform this function.

e. Responsibility of the COE LSMM/AMM

(1) The COE LSMM/AMM (IMMO/State Maintenance Officer) will establish procedures to ensure there is positive control of items identified as PQDR repairs. To assist in that process, they will provide a copy of all SF 368s to the appropriate shop that will perform the initial inspection of the failed item. The shop will ensure that all items received will be compared against all open SF 368s until a match is obtained. The repairing activity will contact, as they determined necessary, the initiator of the PQDR to obtain additional information or further clarify the events resulting in the failure of the item.

(2) Upon completion of the maintenance activity quality investigation, a memorandum response (Reference enclosure 9-5) will be sent from the maintenance activity through the Owning AMM/LSMM to the customer who initiated the PQDR. The written response will address the findings of the quality investigation and any actions taken by the maintenance activity to improve the quality process. (Note: If the item was not returned to the maintenance activity, the LSMM/AMM will review the details of the SF 368 (block 22) along with any other SF 368s received on a similar line and will determine if any corrective actions are warranted.)

(3) Pay all costs for repair, to include shipment to and from the maintenance activity, for those failures which occurred due to workmanship or mechanical defect. Charge to the owning installation's MIPR the cost for repair and transportation for those failures which occurred due to misuse, mishandling, improper installation, improper operation, unauthorized repairs, or unauthorized alterations.

f. RSMM/TSMM responsibilities

(1) Maintain a data table in EMIS 3.0 of regional PQDRs.

(2) Perform trend analysis from a regional perspective of PQDR results. Negative trends will be considered in reviewing maintenance activity performance.

(3) Monitor open PQDRs IAW regional time line (Reference enclosure 9-6)

(4) Arbritates final results of PQDRs when necessary. When reviewing disputed findings, the RSMM/TSMM may call upon other

technical resources in arriving at a final conclusion.

g. Initiating Unit/Maintenance Activity responsibilities

(1) Units suspecting an initial failure will prepare an SF 368 IAW DA PAM 738-750 or DA PAM 738-751 (aviation) and contact their supporting LAR or MA QA/QC Inspector to validate the failure.

(2) If the owning organization takes exception to the final disposition of the PQDR, they will submit their concerns in writing to the RSMM/TSMM for resolution. In the event the RSMM/TSMM cannot resolve the issue, the matter will be referred to the NSMM. The decision of the NSMM is final. The issue should be resolved in 45 days.

h. NSMM responsibility

The NSMM monitors and accesses the regional/theater databases to assist in resolving PQDR issues elevated from the RSMM/TSMM. The PQDR database will be used by the NSMM to monitor reoccurring equipment failures and to analyze the quality system for improvement.

9-10. Regional PQDR oversight

a. The RSMM/TSMM will establish and maintain a PQDR database of local and regional ISM repairs. This database will not include national repair PQDRs. In the majority of cases, the RSMM/TSMM will resolve all disputes concerning the validity of a PQDR for regional/theater work. If, for whatever reason, the dispute cannot be resolved, provisions of paragraph 9-5 will apply.

b. PQDRs for local or regional ISM warranty work will be used to identify and correct quality deficiencies and trends within repairing activities. A valid PQDR is one that meets the following criteria:

(1) The item failed within 30 days of being put into service.

(2) An LAR/QC inspector performed an on-site inspection of the item prior to its removal from the component or end item.

(3) An LAR/QC inspector validated the failure.

(4) An LAR/QC inspector signed and dated the PQDR. The PQDR date will be the date of inspection by the LAR/QC inspector.

(5) The item was returned to the repairing activity that repaired the item for warranty repair unless an agreement was reached between the owning LSMM and the repairing LSMM concerning where the repair should be accomplished.

c. PQDRs that meet the above criteria will be considered in evaluating quality processes at the repairing activity. The following procedures will apply to valid PQDRs:

(1) The investigation of PQDRs and corrective/preventative actions will be taken in accordance with the repairing activity's quality system (ISO 9002).

(2) Upon completion of the repairing activity's quality review process, a copy of the findings and actions taken for each PQDR will be forwarded to the LSMM/AMM. The LSMM/AMM will forward copies to the RSMM/TSMM whom in turn will forward copies to the NSMM.

d. PQDRs that do not meet the criteria in paragraph 9-9.b. will be returned without action and will not be processed as a PQDR.

e. LSMM/AMMs will track the flow of COE PQDRs, equipment improvement reports (EIRs) and RODs, and forward copies of all discrepancy/deficiency reports to the RSMM/TSMM who in turn will forward to the NSMM.

9-11. Internal audit systems

a. Establishing an internal auditing system should be one of the first orders of business for the MA's since it is critical to ensuring a successful quality repair program. The primary goal of the internal audit is to evaluate the operational effectiveness of the quality system. It is a tool for making improvements and should enhance quality within the work centers. An effective quality system audit will provide:

(1) An evaluation of current performance.

(2) An evaluation of current system capability.

(3) Improved communication and motivation.

(4) Factual and unbiased input for decision-making.

(5) Identification of opportunities for improvement.

(6) Identification of training needs and effectiveness.

b. When planning an internal quality system audit, positive programs must be established to audit all elements of ISM maintenance activity operations. Audit plans should include:

(1) Audit team: List the lead auditor and the members of the audit team. No more than six members should comprise an audit team and no more than two members should interview an individual at any given time.

(2) Audit scope: Set the audit boundaries, such as the specific organization's activities and processes slated for review. All quality system elements will be formally audited, as a minimum, annually.

(3) Performance standards: List the specific criteria against which the activity will be audited. The criteria typically are the quality manual policies, implementing procedures, and supporting documentation.

(4) Audit schedule: List major audit activities, responsibilities and expected completion dates. All quality elements must be audited annually.

(5) Interviews: List everyone that must be interviewed in order to determine the system's effectiveness.

(6) Checklist: Checklists should be prepared for each interview and each activity that is to be reviewed. Checklists help auditors organize all of the key points and requirements from the various documents that are viewed as performance standards and ensure all points are adequately covered during the audit. Enclosure 9-2 includes typical checklist-questions than can be used to determine each of the standards requirements.

c. Conducting an internal quality system audit: Audits should not be punitive in nature; rather, they are an effective mechanism for ensuring continuous improvement. They should provide management with unbiased answers to several important questions.

(1) Does the audited activity have proper documents such as an approved Level A quality manual; Level B implementing procedures; and Level C supporting documentation such as quality plans, job descriptions, specific work procedures, checklists, charts, graphs, records and reports?

(2) Do current practices meet requirements outlined in the policies and procedures?

(3) Is the entire system effective in meeting its intended purpose?

(4) How can the system be improved?

d. Collecting verifiable evidence: By reviewing appropriate records and conducting interviews with personnel directly involved in the activity, internal audits can collect verifiable evidence of quality awareness. All conclusions must be based on observed facts that cannot

be disputed. The burden of proof regarding noncompliance is on the auditor. Opinions should never enter into audit results. However, identification of noncompliance should not be the total focus of the audit. The audit should also note system strengths and outstanding performance. This helps avoid the frequent negative perception of auditing.

e. Reporting audit results:

(1) Two types of noncompliance are typically reported.

(a) Observations: Observations are statements of facts substantiated by objective, verifiable evidence accumulated during the audit process. Verifiable evidence includes qualitative and quantitative information, records, data and statements made during interviews that support the observation. Observations indicate the presence of system weaknesses, but do not necessarily lead to the conclusion that the entire system is ineffective. Observations should be viewed as opportunities for making system enhancements.

(b) Findings: Findings are statements of fact identifying a significant system non-compliance, which, if not corrected, could render the system ineffective. Findings may be of a major or minor nature. A major non-conformity report addresses a serious deficiency that could adversely affect quality of the product or services. It may be a complete absence or complete breakdown of a required system. A minor non-conformity report is used when a temporary failure to meet the quality system requirements occurs, but is not significant enough to be a major issue. Both types of findings require corrective action reports.

(2) A report of all findings will be forwarded through the RSMM/TSMM to the NSMM within 30 days from date of the inspection. The report will include the completed checklist along with a definitive assessment of compliance with established standards accompanied by significant observations relative to the audit objective plus sufficient and relevant information on evidence including explanations and comments. Observations should be ranked by importance and arranged in a logical order. This report will also have a timetable for correcting all non-compliance, not to exceed 60 days.

(3) Results of corrective actions will be reported through the RSMM/TSMM to the NSMM. MA will not be eligible to compete for COE or National work if they fail to meet the annual audit requirement. .

f. The duties and responsibilities of the internal audit members are:

(1) Lead Auditor
(a) Assist in selection of other audit team members
(b) Prepare the audit plan
(c) Represent the audit team to the auditee management
(d) Submit the audit report
(e) Plan the audit
(f) Prepare work documents
(g) Brief the audit team
(h) Review existing quality system documentation to determine adequacy
(i) Report critical nonconformance to the audit immediately
(j) Report major obstacles encountered in performing the audit
(k) Report results clearly, conclusively, and without delay.
(l) Submit formal report to the auditee.

(2) Auditor
(a) Supports the lead auditor
(b) Well versed in the types of quality and product specifications the audit is using
(c) Perform assigned tasks in a timely and professional manner
(d) Review objective evidence and decide whether a nonconformance exists
(e) Assure that all findings and non-conformances are documented
(f) Follow the audit plan

(3) Auditee

(a) Appoint lead auditor
(b) Correct all findings of the audit team
(c) Forward a copy of all findings and corrected actions to the NSMM through the RSMM/TSMM and LSMM.

(4) LSMM with AMMs
(a) Provide leadership in quality
(b) Review and evaluate all internal findings and corrected actions taken
(c) Assist in any way requested whenever practical.
(d) Forward results of the audit to the RSMM/TSMM

(5) RSMM/TSMM
(a) Provide leadership in quality
(b) Review and evaluate all internal findings and corrected actions taken
(c) Assist in any way requested.
(d) Forward results of the audit to the NSMM

(6) NSMM
(a) Provide leadership in quality
(b) Review and evaluate all internal findings and corrected actions taken
(c) Assist in any way requested.

9-12. External Audit and assistance program

a. The audit team's primary objective is to review the quality program as implemented and to ensure all requirements of ISO 9002 are met. Level B implementing procedures and Level C supporting documentation must be implemented and available to the work force. To ensure compliance with the ISO 9002 standards, the assessment will involve a close, in-depth appraisal of all the maintenance activity's procedures and systems relating to quality. It will not be sufficient to have only needed documentation, such as quality manuals, but the maintenance activity must demonstrate the practical and effective application of those systems and procedures. In addition, they must provide records to verify that quality systems are ongoing and effectively utilized.

b. The NSMM will conduct a desk side audit of the quality manual, implementing procedures and internal audit results prior to the on site visit. The maintenance activity will provide the required information within 30 days prior to the date of the scheduled audit. An external audit will not be conducted until the documented quality system has been implemented and a formal internal audit conducted.

c. The assessment will follow procedures similar to those used with internal audits as noted in paragraph 9-10. Documentation for the internal audit should serve as the foundation for the external audit.

d. The assessment will normally utilize the following procedure:

(1) The audit team will ask to speak to the personnel responsible for performing a specific activity. The audit team will ask each person to briefly explain how he or she performs their job and fulfills their key responsibilities. Normally these exchanges are general in nature and should be open ended, such as, "Please explain your incoming material inspection procedure?"

(2) The team will then switch to questions such as, "How do you know that is what you are supposed to do?" The intent is to review how and where the activity is documented. Documentation is not necessarily a written procedure. Needed documentation may be training records, flowcharts or sketches.

(3) The team will want to see verifiable evidence that a quality system is in place, such as, Level C documentation.

(4) The team will record comments, names, observations and general notes. Findings or observations will be made only when the auditor discovers deviations from requirements, observes noncompliance with documented procedures or identifies incomplete or missing records.

(5) Upon audit completion, maintenance activity management will be briefed on findings and observations and be given a copy of the auditor's notes. Within 30 days from the inspection date, a written report will be forwarded through the RSMM/TSMM and LSMM to the maintenance activity manager. The report will include a definitive assessment of compliance with established standards along with significant observations and/or findings relative to the audit objective. Sufficient and relevant information regarding evidence along with explanations and comments will be in the report. Both observations and findings will be ranked by importance and arranged in logical order prior to the scheduled audit.

(6) When needed, corrective action reports will be sent through the LSMMs, then RSMM/TSMM to the NSMM within sixty (60) days of receipt of original report. Failure to comply may result in suspension of bid privileges.

9-13. Repair program component markings

a. Mark the outside of the container/box by placing a fluorescent green stick-on-label (ISM in black letters) on the side and in the middle of the container/box. The shipping container or packaging for the component will be marked with the component serial number. The repairing maintenance activity will ensure that only the serial number of the repaired components in the container appears on the outside of the container. All other serial numbers and remarking will be removed.

b. Documentation will be included with the repaired component to provide the customer clear identification of the repairing maintenance activity and procedures to obtain warranty support should it become necessary. All documentation accompanying the item will be complete and legible. Documentation, to be placed in the container or package, will include as minimum;

(1) Serviceable Tag, DA From 1574, attached to the component.

(2) Copy of the ISM regional/COE warranty fact sheet (Reference enclosure 9-4).

(3) Oil Analysis Request Form, DA Form 2026, with results annotated. (if applicable)

(4) Maintenance Request Form, DA From 2407 or STAMIS generated form used in lieu of.

(5) Final Inspection Test Results appropriate to the item (e.g. Dynamometer, EQUATE) signed by the operator/QC.

(6) Component Removal and Repair/Overhaul Record DA Form 2410 (Selected aviation items only)

c. The warranty information fact sheet will be included with each repaired component. Sample warranty information fact sheets are enclosed (Enclosures National 9-3 or Regional 9-4). Maintenance activity will provide their name, address, and phone numbers in the location identified in bold on the form. The signature of the final inspectors signifies that the product meets all final test requirements and is ready for issue.

d. A label made of material suitable to the repaired component will be permanently affixed to the component in a prominent location. Labels will be replaced each time the item is received for repair. Data plates or overhaul labels from depot level activities will not be removed. The labels will contain the following information:

(1) Name of the repairing maintenance activity

(2) Date Repaired

(3) Work Order Number

(3) National Stock Number of the repair component

(4) Serial Number of the repaired component

(5) LSMMs/AMMs DSN and commercial phone number

Note: Label Exception - Items 1,2 and 3 are the minimum essential items. Items 4, 5 and 6 will only be omitted if the component does not lend itself to a label of sufficient size to include the information (e.g. CCAs).

e. The repairing maintenance activity will be identified in all documentation including the label by the government activity represented. (e.g., DOL Ft Riley, KS, MIARNG, CSMS, DOL Ft Hood Aviation Maintenance Activity) Telephone numbers provided will be to the LSMM office.

9-14. Processing a COE Report of Discrepancy (ROD)

a. Any LSMM/AMM that desires or requests special consideration by the RSMM/TSMM when performance is computed or during the IFB process will provide sufficient information to document their position. Examples are copies of RODs containing the information in figure 9-1 with supporting completed work orders reflecting the missing parts, which were charged to the work order. A valid ROD will include all items listed in paragraph 9-12.b, Figure 9-1and have an authorized quality control and/or quality assurance representative's signature. Incomplete RODs will be returned by the LSMMs to the quality control /assurance section for corrective action. RODs must include the case number (if one was created) and the repairing activity WON. Incomplete RODs will not be accepted by the LSMM/AMM. Labor charges are not included in the ROD charges.

b. IAW 735-11-2 RODs will be submitted or accepted for:

(1) Materiel received for repair which has missing parts, been cannibalized of non-expendable parts or components (including cannibalization of non-expendable Basic Issue Item (BII) or a non-expendable AMC centralized management reparable item/part without the authorization of the item manager when the total value of missing item(s) is in excess of $100. (Note: Expendable BII and expendable spare/repair parts are not subject to the aforementioned procedures.) The repairing activity will charge any additional costs to repair damaged parts and components to the shipping installation's MIPR.

(2) Any unsatisfactory condition resulting from improper packaging which causes or renders the item, shipment, package, or container to be vulnerable to any loss, delay, or damage when the estimated or actual cost of correction exceeds $50. Packaging RODs will be initiated upon receipt of the item. The repairing activity will charge any additional packaging costs and costs to repair to the shipping installation's MIPR.

c. The repairing activity will document any missing parts that are identified in the component configuration using the ROD (SF 364) accompanied by a copy of the completed work order for the item being repaired, with charges for missing parts identified on the work order. The repairing activity may only submit RODs for missing parts to the owning LSMM/AMM in those instances where the repairing MA purchased the missing parts and charged the work order. Missing parts will be billed against the work order. Reimbursement for other than missing parts will be processed and charged against the shipping installation's MIPR using the SF 364 (IAW 735-11-2).

(1) The LSMM/AMM initiating the ROD will fax a copy of the ROD and completed work order (for missing parts) to the LSMM/AMM being charged. The ROD will include the information contained in figure 9-1.

(2) The LSMM/AMM will process the ROD through their servicing financial office in accordance with local procedures.

Case number
NIIN for the COE item
COE work order number for the component
Serial number of the COE component
NIIN for the missing part
Nomenclature for the missing part
AMDF price for the missing part
Total cost of missing parts charged to the work order.
Name of authorized quality control/ assurance representative signing the ROD

Figure 9-1

Enclosure 9-1 **International Organization for Standardization (ISO)**

ISO9002

ADOPTION NOTICE

ISO9002, "Quality Systems - Model for Quality Assurance in Production, Installation and Servicing", was adopted on 01-JUL-94 for use by the Department of Defense (DoD). Proposed changes by DoD activities must be submitted to the DoD Adopting Activity: Manufacturing and Quality Division, SAF/AQXM, 1060 Air Force Pentagon, Washington, DC 20330-1060. DoD activities may obtain copies of this standard from the Standardization Document Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 19111-5094. The private sector and other Government agencies may purchase copies from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036.

Custodians:
Army - AR
Navy - OS
Air Force - 05

Adopting Activities:
Air Force - 05

Reviewer Activities:
Army - AV, CR, CR4, GL
Navy - AS, EC, MC, SA, SH, TD
Air Force - 10
DLA - DH

FSC QCIC

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INTERNATIONAL STANDARD

ISO 9002

Second edition
1994-07-01

Quality systems — Model for quality assurance in production, installation and servicing

Systèmes qualité — Modèle pour l'assurance de la qualité en production, installation et prestations associées

Reference number
ISO 9002:1994(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9002 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This second edition cancels and replaces the first edition (ISO 9002:1987), which has been technically revised.

Annex A of this International Standard is for information only.

Introduction

This International Standard is one of three International Standards dealing with quality system requirements that can be used for external quality assurance purposes. The quality assurance models, set out in the three International Standards listed below, represent three distinct forms of quality system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

a) ISO 9001, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*

   — for use when conformance to specified requirements is to be assured by the supplier during design, development, production, installation and servicing.

b) ISO 9002, *Quality systems — Model for quality assurance in production, installation and servicing*

   — for use when conformance to specified requirements is to be assured by the supplier during production, installation and servicing.

c) ISO 9003, *Quality systems — Model for quality assurance in final inspection and test*

   — for use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.

It is emphasized that the quality system requirements specified in this International Standard, ISO 9001 and ISO 9003 are complementary (not alternative) to the technical (product) specified requirements. They specify requirements which determine what elements quality systems have to encompass, but it is not the purpose of these International Standards to enforce uniformity of quality systems. They are generic and independent of any specific industry or economic sector. The design and implementation of a quality system will be influenced by the varying needs of an organization, its particular objectives, the products and services supplied, and the processes and specific practices employed.

It is intended that these International Standards will be adopted in their present form, but on occasions they may need to be tailored by adding or deleting certain quality system requirements for specific contractual situations. ISO 9000-1 provides guidance on such tailoring as well as on selection of the appropriate quality assurance model, *viz.* ISO 9001, ISO 9002 or ISO 9003.

INTERNATIONAL STANDARD © ISO ISO 9002:1994(E)

Quality systems — Model for quality assurance in production, installation and servicing

1 Scope

This International Standard specifies quality system requirements for use where a supplier's capability to supply conforming product to an established design needs to be demonstrated.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from production through to servicing.

International Standard is applicable in situations when

a) the specified requirements for product are stated in terms of an established design or specification, and

b) confidence in product conformance can be attained by adequate demonstration of a supplier's capabilities in production, installation and servicing.

NOTE 1 For informative references, see annex A.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 and the following definitions apply.

3.1 product: Result of activities or processes.

NOTES

2 A product may include service, hardware, processed materials, software or a combination thereof.

3 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

4 For the purposes of this International Standard, the term "product" applies to the intended product offering only and not to unintended "by-products" affecting the environment. This differs from the definition given in ISO 8402.

3.2 tender: Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

3.3 contract: Agreed requirements between a supplier and customer transmitted by any means.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure

that this policy is understood, implemented and maintained at all levels of the organization.

4.1.2 Organization

4.1.2.1 Responsibility and authority

The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system;

b) identify and record any problems relating to the product, process and quality system;

c) initiate, recommend or provide solutions through designated channels;

d) verify the implementation of solutions;

e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.2 Resources

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

4.1.2.3 Management representative

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for

a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and

b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE 5 The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

4.1.3 Management review

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

4.2 Quality system

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 6 Guidance on quality manuals is given in ISO 10013.

4.2.2 Quality system procedures

The supplier shall

a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy, and

b) effectively implement the quality system and its documented procedures.

For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

NOTE 7 Documented procedures may make reference to work instructions that define how an activity is performed.

4.2.3 Quality planning

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

a) the preparation of quality plans;

b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality;

c) ensuring the compatibility of the production process, installation, servicing, inspection and test procedures and the applicable documentation;

d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;

e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;

f) the identification of suitable verification at appropriate stages in the realization of product;

g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

the identification and preparation of quality records (see 4.16).

NOTE 8 The quality plans referred to [see 4.2.3 a)] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

4.3 Contract review

4.3.1 General

The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.

4.3.2 Review

Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that:

a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;

b) any differences between the contract or order requirements and those in the tender are resolved;

c) the supplier has the capability to meet the contract or order requirements.

4.3.3 Amendment to a contract

The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

4.3.4 Records

Records of contract reviews shall be maintained (see 4.16).

NOTE 9 Channels for communication and interfaces with the customer's organization in these contract matters should be established.

4.4 Design control

The scope of this International Standard does not include quality-system requirements for design control. This subclause is included to align the clause numbering with ISO 9001.

4.5 Document and data control

4.5.1 General

The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.

NOTE 10 Documents and data can be in the form of any type of media, such as hard copy or electronic media.

4.5.2 Document and data approval and issue

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essen-

tial to the effective functioning of the quality system are performed;

b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

4.5.3 Document and data changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

4.6 Purchasing

4.6.1 General

The supplier shall establish and maintain documented procedures to ensure that purchased product (see 3.1) conforms to specified requirements.

4.6.2 Evaluation of subcontractors

The supplier shall:

a) evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;

b) define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors;

c) establish and maintain quality records of acceptable subcontractors (see 4.16).

4.6.3 Purchasing data

Purchasing documents shall contain data clearly describing the product ordered, including where applicable:

a) the type, class, grade or other precise identification;

b) the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;

c) the title, number and issue of the quality system standard to be applied.

The supplier shall review and approve purchasing documents for adequacy of the specified requirements prior to release.

4.6.4 Verification of purchased product

4.6.4.1 Supplier verification at subcontractor's premises

Where the supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents.

4.6.4.2 Customer verification of subcontracted product

Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.

Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

4.7 Control of customer-supplied product

The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is

herwise unsuitable for use shall be recorded and ported to the customer (see 4.16).

Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

4.8 Product identification and traceability

Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation.

Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

4.9 Process control

The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;

b) use of suitable production, installation and servicing equipment, and a suitable working environment;

c) compliance with reference standards/codes, quality plans and/or documented procedures;

d) monitoring and control of suitable process parameters and product characteristics;

e) the approval of processes and equipment, as appropriate;

f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations);

g) suitable maintenance of equipment to ensure continuing process capability.

here the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified.

NOTE 11 Such processes requiring pre-qualification of their process capability are frequently referred to as special processes.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see 4.16).

4.10 Inspection and testing

4.10.1 General

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

4.10.2 Receiving inspection and testing

4.10.2.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures.

4.10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

4.10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

4.10.3 In-process inspection and testing

The supplier shall:

a) inspect and test the product as required by the quality plan and/or documented procedures;

b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when

product is released under positive-recall procedures (see 4.10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 4.10.3 a).

4.10.4 Final inspection and testing

The supplier shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

4.10.5 Inspection and test records

The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records shall identify the inspection authority responsible for the release of product (see 4.16).

4.11 Control of inspection, measuring and test equipment

4.11.1 General

The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation or servicing, and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).

Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.

NOTE 12 For the purposes of this International Standard, the term "measuring equipment" includes measurement devices.

4.11.2 Control procedure

The supplier shall:

a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision;

b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;

c) define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;

d) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

e) maintain calibration records for inspection, measuring and test equipment (see 4.16);

f) assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;

ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

h) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;

i) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

NOTE 13 The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.

4.12 Inspection and test status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and serving of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used or installed.

4.13 Control of nonconforming product

4.13.1 General

The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

4.13.2 Review and disposition of nonconforming product

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be

a) reworked to meet the specified requirements,

b) accepted with or without repair by concession,

c) regraded for alternative applications, or

d) rejected or scrapped.

Where required by the contract, the proposed use or repair of product [see 4.13.2 b)] which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).

Repaired and/or reworked product shall be reinspected in accordance with the quality plan and/or documented procedures.

4.14 Corrective and preventive action

4.14.1 General

The supplier shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

4.14.2 Corrective action

The procedures for corrective action shall include:

a) the effective handling of customer complaints and reports of product nonconformities;

b) investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation (see 4.16);

c) determination of the corrective action needed to eliminate the cause of nonconformities;

d) application of controls to ensure that corrective action is taken and that it is effective.

4.14.3 Preventive action

The procedures for preventive action shall include:

a) the use of appropriate sources of information such as processes and work operations which af-

fect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyse and eliminate potential causes of nonconformities;

b) determination of the steps needed to deal with any problems requiring preventive action;

c) initiation of preventive action and application of controls to ensure that it is effective;

d) ensuring that relevant information on actions taken is submitted for management review (see 4.1.3).

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 General

The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.

4.15.2 Handling

The supplier shall provide methods of handling product that prevent damage or deterioration.

4.15.3 Storage

The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

4.15.4 Packaging

The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

4.15.5 Preservation

The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

4.15.6 Delivery

The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

4.16 Control of quality records

The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

NOTE 14 Records may be in the form of any type of media, such as hard copy or electronic media.

4.17 Internal quality audits

The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).

'OTES

) The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3).

16 Guidance on quality system audits is given in ISO 10011.

4.18 Training

The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 4.16).

4.19 Servicing

Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.

4.20 Statistical techniques

4.20.1 Identification of need

The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

4.20.2 Procedures

The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

Annex A
(informative)

Bibliography

[1] ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use.*

[2] ISO 9000-2:1993, *Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003.*

[3] ISO 9000-3:1991, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software.*

[4] ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

[5] ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test.*

[6] ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

[7] ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors.*

[8] ISO 10011-3:1991, *Guidelines for auditing quality systems — Part 3: Management of audit programmes.*

[9] ISO 10012-1:1992, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment.*

[10] ISO 10013:—[1], *Guidelines for developing quality manuals.*

[11] ISO/TR 13425:—[1], *Guidelines for the selection of statistical methods in standardization and specification.*

1) To be published.

Enclosure 9-2 **ISM Quality Systems Audit Checklist**

AUDIT CHECKLIST

Company Name: **Audited By:** **Date:**

Compliance Status S = Satisfactory D = Deficient NA = Not applicable/Not available				
Status			**Requirements** Corresponding to clauses of ISO 9002	**Comments** Write explanations, comments on deficiency, verification, or objective evidence, and record names, document numbers and revision status. Use attachments as necessary.
S	**D**	**N**		
			4.1 Management Responsibility	
			4.1.1 Quality Policy	
			a. Is the company policy on quality documented? b. Have specific goals/objectives been established? c. Are these goals/objectives realistic and measurable? d. Has the policy, along with goals/objectives been published and distributed? e. Is the quality policy, along with goals/objectives known and understood by staff personnel at all levels? f. Is management's role in quality clearly defined?	
			4.1.2 Organization	
			Does the Quality Manual include an organizational chart illustrating staff relationships and the executing organization structure?	
			4.1.2.1 Responsibility and Authority	
			a. Have responsibilities and authority of all personnel, (management, performance, and verification) whose actions affect quality been defined and documented (matrix)? b. Where are these responsibilities documented in their job descriptions?	

			4.1.2.2 Resources	
			a. Have adequate resources been identified to implement the Quality System? b. Are sufficient trained personnel available to manage QA, perform the work, verify quality, and perform internal audits?	
			4.1.2.3 Management Representative	
			a. Has a management representative been assigned to ensure that ISO 9002 requirements are implemented and maintained? b. Are there procedures for reporting Quality System performance to management?	
			4.1.3 Management Review	
			a. Is management, with executive responsibility for the Quality System, actively conducting periodic reviews? b. Are reviews documented, records maintained, and available?	
			4.2 Quality System	
			4.2.1 General	
			a. Does the Quality Manual include or refers to the documented Quality System procedures? b. Does the Quality Manual identify who has responsibility to maintain and/or review the Quality System to include internal audits? c. Has the Quality Manual been distributed to, and understood by those having direct responsibility for management of the Quality System? d. Has a documented Quality System been established and implemented at all levels of the organization?	
			4.2.2 Quality System Procedures	

			a. Are Quality System procedures clearly written in a manner that is consistent with the skills, methods, and training level of personnel using them? b. Has the Quality System been effectively implemented within the organization to assure product quality?	
			4.2.3 Quality Planning	
			a. Are there documented policies, procedures, and/or work instructions for the preparation of quality plans and are they properly followed? b. Is there a systematic method or procedures available to identify the proper human and capital resources and methods needed to achieve the required levels of quality? c. Are there procedures to ensure that production process, installation, servicing, inspection, and testing are compatible with the Quality System, work instructions, and quality planning documentation? d. Are there procedures in place for updating control, inspection, testing, and identification of new quality measurement requirements? e. Are measurement requirements identified in sufficient time for measurement techniques to be developed prior to production? f. Are there documented procedures or work instructions to determine product quality characteristics for verification at various stages of production? g. Are there standards of acceptability for all features and requirements, including cosmetic and other visual verification that require a subjective evaluation? h. Is there documentation that clearly defines the requirement for and nature of the Quality System records?	
			4.3 Contract Review	

			4.3.1 General	
			a. Is a procedure for examining and reviewing contract requirements defined and documented? b. Are personnel involved in contract review knowledgeable of procedural requirements?	
			4.3.2 Review	
			a. Does the procedure ensure that customer requirements are adequately defined and documented prior to acceptance of an order or contract? b. Does the procedure adequately provide for coordination by all affected personnel? c. Are procedures available to resolve differences between the contract and tender? d. What process is used to review capability to meet accepted order requirements?	
			4.3.3 Amendment To Contract	
			a. Are procedures available to handle verbal changes? b. Is there an effective way to incorporate revisions after the project has been initiated?	
			4.3.4 Records	
			Are complete and accurate records of contract reviews maintained and for how long?	
		N	**4.4 Design Control**	
			4.5 Document and Data Control	
			4.5.1 General	
			a. Have procedures been established and maintained for the control of all documents? b. Is there a master list with a numbering system and is it effective?	

			4.5.2 Document Approval and Issue	
			a. Do procedures require that controlled documents be reviewed for adequacy by authorized personnel prior to issue? b. Is there a system in place to assure that controlled documents are kept current? c. Is there a master list of all controlled documents that identifies the current revision? d. Are all controlled documents identified with a current revision number? e. Is there a clear definition of responsibilities for issue, distribution, maintenance, and revision of controlled documents? f. Are the appropriate documents available at all locations where operations essential to the effective functioning of the quality systems are performed?	
			4.5.3 Document Changes	
			a. Is there a system in place to promptly remove all obsolete documents? b. Are changes to documents reviewed and approved by persons or functions who originally reviewed and approved the documents?	
			4.6 Purchasing	
			4.6.1 General	
			Are there documented procedures to ensure purchased products conform to specified requirements?	
			4.6.2 Evaluation of Sub-contractors	
			a. Are there documented procedures to cover selection of all subcontractors? b. Has an approved subcontractor list been established and maintained based on performance reviews and supplier's capability verses requirements?	

			4.6.3 Purchasing Data		
			a. Does purchasing documentation contain data that clearly describe the product ordered? b. Are purchasing documents reviewed and approved for adequacy of specified requirements prior to order release?		
			4.6.4 Verification of Purchased Data		
			Is there a procedure to report material/parts that are found to be unsuitable for use?		
			4.7 Control of Customer Supplied Product		
			a. Are there documented procedures for the verification, storage, and maintenance of customer supplied products? b. Are procedures in place for establishing a system of recording and reporting products lost, damaged, or unsuitable for use?		
			4.8 Product Identification and Traceability		
			a. Are documented procedures in place for identifying a product from receipt through all stages of production, delivery, and installation? b. Where traceability is a requirement, do documented procedures exist for individual products or batches to have unique identification? c. Based on randomly sampled observations on the shop floor, is there evidence that any floor stocked item cannot be easily and correctly identified? d. Is nonconforming material held for disposition always clearly identified? e. Are complete and accurate records kept of product and material history, including the material and product original lot or batch information?		

			4.9 Process Control	
			a. Are documented procedures in place for reviewing, controlling, and updating work instructions? b. Are Quality Plans available and being used? c. Is there a process to assure production is accomplished under controlled conditions? d. Is production in compliance with referenced standards or documented procedures? e. Is suitable maintenance of equipment being done? f. Are documented work instructions readily available to all those who could use them? g. Are records of qualified processes, equipment, and personnel appropriately maintained?	
			4.10 Inspection and Testing	
			4.10.1 General	
			a. Are there documented procedures for inspection and testing activities in order to verify that specified requirements for the product are met? Are these procedures reflected in a specific item Quality Plan or an approved document?	
			4.10.2 Receiving, Inspecting, and Testing	
			Have Quality Plans or documented procedures been developed for verification of incoming product to ensure conformance to specified requirements?	

			4.10.3 In-Process Inspection and Testing				
			a. Do Quality Plans or documented procedures specify all in-process inspection and testing requirements? b. Do procedures allow visibility of inspection status during in-process production? c. Are documented procedures available to control shelf life items? d. Are procedures available for handling nonconforming products? e. For urgently released products are test and inspections still being completed?				
			4.10.4 Final Inspection and Testing				
			a. Are procedures documented for final testing and inspection? b. Do procedures ensure that all previous inspection and testing meet specified requirements? c. Do procedures preclude the shipping of finished product until all required inspections and tests have been completed?				
			4.10.5 Inspection and Test Records				
			a. Has the unit established and maintained records that provide evidence of product passing inspection and/or tests? b. Do records identify the inspection authority responsible for the release of product?				
			4.11 Control of Inspection, Measuring, and Test Equip				

			4.11.1 General	
			a. Are there documented procedures to control, calibrate, and maintain all measuring and test equipment? b. Do procedures include a method of calibration, acceptance criteria, and action to be taken when results are unsatisfactory and extent/frequency of checks ?	
			4.11.2 Control Procedures	
			a. Is equipment calibrated at appropriate intervals to recognized national standards? b. Are there procedures to notify personnel if equipment requires calibration? c. Do procedures require equipment be labeled to indicate calibration status? d. Do procedures require that the validity of previously inspections and tests be reassessed when equipment is found to be out of calibration? e. Do procedures require calibration records be maintained?	
			4.12 Inspection and Test Status	
			a. Is inspection and test status maintained as specified in the Quality Plan and/or in documented procedures? b. Do documented procedures provide for the identification of inspection/status such as: awaiting inspection, inspected and accepted, inspected and rejected? c. Do procedures require identifying the person authorizing release of conforming product be recorded and maintained?	
			4.13 Control of Nonconforming Product	

			4.13.1 General				
			a. Are there documented procedures to ensure products that do not conform to specified requirements are prevented from unintended use or installation? b. Do procedures define the responsibility for review and the authority for decision of nonconforming product? c. Are procedures correctly and consistently followed and is it effective in preventing the use of nonconforming material in all stages of production? d. Is there a designated or clearly identified "bond area" to prevent inadvertent use of nonconforming material?				
			4.13.2 Nonconforming Product Review and Disposition				
			a. Do procedures provide for identification, documentation, evaluation, segregation, disposal, and notification to the functions concerned? b. Does it address the responsibilities and steps to follow in order to identify and assemble personnel with appropriate knowledge, responsibility, and authority to determine product disposition? c. Are records maintained of meetings designed to handle disposal of scrap and rework?				
			4.14 Corrective and Preventative Action				
			4.14.1 General				
			a. Have documented procedures been established for implementing corrective and preventative actions? b. Are changes documented to prevent recurrence? c. Is there adequate knowledge, understanding, and commitment on the part of senior management and the staff regarding corrective and preventative actions?				

			4.14.2 Corrective Action		
			a. Are there documented procedures for investigating nonconforming products as a result of either customer complaints or product test failures? b. Do procedures allow for applying controls to ensure that corrective actions are effective?		
			4.14.3 Preventative Action		
			a. Are there procedures for identifying and implementing action to prevent recurrence. b. Do procedures ensure that relevant information of action taken are submitted for management review? c. Does senior management take pro-active steps directing process reviews?		
			4.15 Handling, Storage, Packaging, Preservation, and Delivery		
			4.15.1 General		
			a. Are there documented procedures for the handling, storage, packaging, preservation, and delivery of products? b. Are special procedures incorporated into specific item Quality Plans?		
			4.15.2 Handling		
			Do procedures prescribe methods that prevent damage or deterioration of product?		
			4.15.3 Storage		
			a. Are there procedures for controlling the receipt and release of products from stock rooms and/or other storage areas? b. Are there procedures for identification and segregation of product and do these procedures cover the assessment of product condition at defined intervals?		

			4.15.4 Packaging	
			Do procedures define the process for packing, packaging, marking, and follow requirements specified in Chapters 5 & 6, ISM BPM, dated 15 Mar 98?	
			4.15.5 Preservation	
			Are there appropriate measures for segregation and preservation of product?	
			4.15.6 Delivery	
			Are there documented procedures to cover protection and quality of product after final inspection and during transit to final destination?	
			4.16 Control of Quality Records	
			a. Are there documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records? b. Does the Quality System ensure that records are satisfactorily stored and readily retrievable and is a retention period stipulated? c. Is the authority and method used to dispose of records defined for each type of record? d. Do the relevant procedures and/or work instructions for the control of quality records provide for backup copies or for other forms of data security on electronic media?	
			4.17 Internal Quality Audits	
			a. Are there procedures that establish a comprehensive system of planned and documented internal quality audits to verify compliance and determine the effectiveness of the Quality System? b. Is the internal audit procedure well understood by all affected personnel?	

			c. Are all personnel involved in the internal audit well informed about the purpose and scope, and are they sufficiently prepared? d. Do management personnel take timely corrective action on deficiencies found by the audit? e. Are records of the audit forwarded through ISM channels? f. Are records available showing implementation and effectiveness of corrective actions taken?	
			4.18 Training	
			a. Are there documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality? b. Has specified training been performed or is an action in place to fill any gaps in training? c. Are there specific procedures for "on-the-job-training?" d. Are there provisions for Quality System awareness education for all new hires? e. Are training records maintained to demonstrate that personnel have been properly trained?	
			4.19 Servicing	
			a. Are there documented procedures for handling customer complaints? b. Do the procedures clearly state how the repairing organization/LSMM will interface with the owning LSMM on options available to resolve warranty claims? c. Do procedures clearly state how warranty claims impact on internal corrective actions as part of the Quality System paragraph 4.14? d. Are records available on all servicing (warranty) claims and actions taken to resolve same?	

			4.20 Statistical techniques		
			4.20.1 Identification of need		
			a. Are there documented procedures that identify a systemic approach for identifying statistical techniques to maintain product quality? b. What systemic approaches are used to identify the need for statistical techniques?		
			4.20.2 Procedures		
			a. Are statistical techniques effectively used in the production, support, and office function areas? b. Are methods for collecting and analyzing quality failure data well understood and consistently used for subsequent analysis and quality improvement projects? c. Is effective use made of charts, graphs, and other formats to display data on quality performance and process improvements? d. Is management effectively utilizing the statistical data?		

Enclosure 9-3 **ISM National Repair Warranty Information Fact Sheet**

ISM NATIONAL REPAIR
WARRANTY INFORMATION FACTSHEET

1. SCOPE: This item is a product of an Integrated Sustainment Maintenance (ISM) National Repair Program. The item was repaired by ***__(filled in by repairing maintenance activity)_____***. RETAIN this document in the LOGBOOK for the end item in which it is installed.

2. TERMS: This ISM repair national warranty guarantees that this item will be free from all defects in material and workmanship for ***(MA will enter warranty specified in the National SOW)***. If a failure does occur, the failure must be validated by the AMC LAR or MA QA/QC representative before the item will be repaired without cost to you upon its return to the designated repairing activity. Prior to removal of the component from the end item, an LAR/QC inspector should perform an on-site inspection of the item. When this is not feasible (for example, the unit is involved in a field training exercise, LAR/MAQC inspector is not available, or otherwise deployed from home station), the unit should segregate the item and initiate a warranty claim at the earliest opportunity. The customer has 60 days to return the item to the specified repairing activity for warranty work. The customer /owning unit is responsible for transportation cost to the repairing activity. The repairing activity is responsible for the cost to return the repaired item to the customer.

3. PROTECT YOUR INVESTMENT:

a. After installation, annotate and enclose the warranty information sheet in the end item's logbook for a minimum of one year.
b. If the item fails, do not attempt to make any repair or adjustment.
c. Do not remove the component from the end item.
d. Any repairs or major adjustments must be approved by the warranting facility.
e. Any unauthorized repairs or adjustments may void the warranty.

4. HOW TO PROCESS A WARRANTY CLAIM: ISM product quality problems are handled through the ISM Management channels. Contact the Local Sustainment Maintenance Manager below and your own LSMM for an MA Quality Assurance/Quality Control (QA/QC) representative, or the appropriate Logistics Assistance Representative (LAR) for assistance. Complete the SF 368 QDR IAW DA PAM 738-750 or DA PAM 738-751 (aviation). If assistance is required, the unit may contact the National Sustainment Maintenance Management (NSMM) Quality Team at 1-800-653-6766. The quality team will assist you in getting in contact with the Regional/Theater Sustainment Maintenance Management Office Quality representative.

5. WORKORDER INFORMATION PROVIDED BY REPAIRING ACTIVITY:

Nomenclature _____

STAMIS WON _____

NSN _____

Serial Number _____

Repair Date _____

6. QUESTIONS: Contact LSMM, Bldg. _____, Ft. _____

E-Mail: _____
Phone: DSN _____ or Commercial (____) _____
FAX: DSN _____ or Commercial (____) _____

Enclosure 9-4 **ISM Regional Repair Warranty Information Fact Sheet**

WARRANTY INFORMATION

This item was repaired by the ***to be filled in by the MA*** using the appropriate equipment technical manual series 10-40 and if applicable, an approved AMC Special Repair Authority under the Integrated Sustainment Maintenance (ISM) program. The ***to be filled in by the MA*** is committed to meeting or exceeding our customer's expectations in terms of the quality of the products that are provided.

As a sign of that commitment, if this item does not perform to your expectations within the first 30 days after it is placed in service, it will be repaired without cost to you upon its return to this repairing activity. RETAIN this document in the LOGBOOK for the end item in which it is installed.

TO OBTAIN WARRANTY SUPPORT:

1. Do not attempt to make any repairs, adjustments or remove any parts from the component.
2. Do not remove the component from the end item in which it is installed.
3. Prepare an SF368 (Quality Deficiency Report), IAW DA PAM 738-750 or DA PAM 738-751 for aviation items.
4. Contact your local DOL or supporting general support maintenance activity for a Quality Assurance/Quality Control (QA/QC) representative and the appropriate Logistics Assistance Representative (LAR). They will validate the failure. . When this is not feasible (for example, the unit is involved in a field training exercise, LAR/MAQC inspector is not available, or otherwise deployed from home station), the unit should segregate the item and initiate a warranty claim at the earliest opportunity.
5. Any repairs or adjustments must be approved by the warranting facility.
6. Any unauthorized repairs or adjustments void this warranty.

NOMENCLATURE: _____
WON _____ NSN: _____
Serial Number_____ Repair Date: _____

FINAL INSPECTION PERFORMED BY _____

Questions? Contact Local Sustainment Maintenance Office, Bldg. 88040, Ft. Swampy, TX 76544
Phone: DSN _____or Commercial _____
Fax: DSN _____or Commercial _____
E-Mail: _____

Enclosure 9-5 **ISM Regional Repair QDR Response Memorandum**

MEMORANDUM THRU: COE LSMM (If response is from an AMM)
FOR: COMMANDER XXXX

SUBJECT: Results of Regional Quality Deficiency Report (QDR) Investigation

1. The Fort Hood DOL received a Quality Deficiency Report (SF 368) on the following item:

a. NSN: Block 5 of SF 368
b. Repairing Maintenance Activity:
c. Original EVAC Case Number: (If applicable)
d. Original WON:
e. QDR EVAC Case Number: (If applicable)
f. QDR WON:
g. Serial Number: (If applicable)
h. Submitted by: Block 1a and 1b of QDR
i. Report Control Number: Block 3 of QDR

2. Failure identified from block 22 of the QDR:

3. Results of quality investigation:

a. Maintenance Activity Fault
b. Customer Fault
c. No Fault Found (MA could not reproduce fault)
d. Not Returned to Maintenance Activity (Includes incorrect serial numbered item returned)

4. Maintenance Findings:

5. Quality process improvements or changes that will be conducted internally to the maintenance repair process or recommended procedures to be reviewed/changed at the initiator level.

6. Point of Contact at the COE LSMM is ….

SIGNATURE OF COE LSMM OR
MAINTENANCE ACTIVITY SUPERVISOR
(Must be Government Representative)

DISTRIBUTION:

Owning LSMM
Supporting LSMM
Supporting LAR
RSMM

Encl(s).

Enclosure 9-6 **ISM Regional Repair QDR Processing Timeline**

This timeline provides an approximate time period for actions in the QDR process to occur. It is intended as a guide. It is recognized that numerous actions may take place in the same day or delays may be experienced outside the time discussed here.

TIME	ACTION or EVENT
DAY 1	Unit identifies quality problem, writes QDR, contacts supporting QA/LAR for validation
DAY 2-3	QA/LAR validates the QDR, assists unit in completion of QDR as necessary, signs copy of QDR, gives copy of QDR to owning LSMM/IMMO. Owning LSMM/IMMO faxes copy of QDR to repairing LSMM and RSMM, LSMMs discuss best repair option (If Appropriate).
DAY 2-15	Unit draws replacement component, turns in QDR item to SSA and ultimately to GS/RX account.
	GS/RX account work orders the component to LSMM who directs repair or shipment to the repairing LSMM.
DAY 30	If the item has not been shipped to repairing LSMM, QDR Representative will verify the status. LSMM QDR representative sends response memorandum closing out the QDR as not returned.
DAY 15 + MTTR	Repairing LSMM repairs the component, determines quality problem and solution, returns the component to owning GS/RX activity, provides results of QDR to owning LSMM and RSMM. If component was not returned, repairing LSMM performs any analysis based on information provided on the QDR and determines if any corrective actions are warranted. He provides this information also to the owning LSMM and RSMM.